By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 655954**

Issued To: **VITREQ B.V.**
Seggelant-Noord 2
Vierpolders
3237 MG
Netherlands

In respect of:

Those aspects of manufacture related to securing and maintaining sterility of vitrectomy sutureless lenses.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **11 July 2016** Date: **11 July 2016** Expiry Date: **16 February 2021**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 655954**
Date:	**11 July 2016**
Issued To:	**VITREQ B.V.** **Seggelant-Noord 2** **Vierpolders** **3237 MG** **Netherlands**

Subcontractor:	**Service(s) supplied**
Rose GmbH Medizin- und Sterilisiertechnik Gottbillstr. 25-30 Trier 54294 Germany	**ETO Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 655954**

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Date	Reference Number	Action
11 July 2016	8555561	First issue.

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